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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,348	03/24/2005	Ilan Shalev	331/04204	5391

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EXAMINER	
MEHTA, BHISMA	
ART UNIT	PAPER NUMBER
3767	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,348	SHALEV, ILAN	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,19-48 and 50-55* is/are pending in the application.

4a) Of the above claim(s) *25,36-38,40-43,48 and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,19-24,26-35,39,44-47 and 51-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 March 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings were received on March 30 2009. These drawings are acceptable.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose a venous port being adapted to be implanted in a surface vein. The specification also fails to disclose relative movement of the plurality of extensions with respect to the at least one aperture, from the first position to the second position, operating to open at least one blood passageway among the plurality of extensions.

Claim Objections

3. Claims 1-15, 19-24, 26-35, 39, 44-47, and 51-55 are objected to because of the following informalities: In line 6 of claim 1, it appears that a punctuation mark is missing after “extensions”. Claim 11 recites the limitation "said surface vein" in line 2. Claim 51 recites the limitation "said patient" in lines 3-4. Claim 54 recites the limitation "said surface vein" in line 1. There is insufficient antecedent basis for these limitations in these claims. It is suggested that “said surface vein" and "said patient" be replaced with “the surface vein" and "the patient", respectively, as parts of the human body or the

patient are not to be claimed. In line 1 of claim 55, it appears that a word is missing before "hollow".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-15, 19-24, 26-35, 39, 44-47, and 51-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of “at least part of said respective extension” in lines 8-9 of claim 1 is unclear as, in the situation of the at least one aperture comprising only one aperture, it would be unclear which extension would be extending away from the one aperture. It is suggested that “at least part of said respective extension extends away from said at least one aperture" be replaced with “at least part of each of said plurality of extensions extends away from said at least one aperture".

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-15, 19-24, 26, 27, 32-34, 39, 44-47, and 51-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yozu et al (U.S. Patent Application Publication No. 2003/0167038).

Yozu et al disclose a venous port having a hollow tube (103, 303, 403) defining at least one aperture (121, 123, 125, 325, 423 – paragraphs [0060] and [0071]) configured for the unimpeded intake of fluid and located on the hollow tube and a plurality of extensions (105, 305, 405) operative to be at at least two positions with respect to the at least one aperture. The venous port of Yozu et al is adapted to be placed through a body tissue and is capable of being implanted in a surface vein. In the first position, each of the plurality of extensions is near at least one aperture. In the second position, at least part of each of the plurality of extensions extends away from at least one aperture. If the at least one aperture is blocked by an impediment, the relative movement of the plurality of extensions with respect to the at least one aperture is considered to be capable of dislodging the impediment from the at least one aperture and opening at least one blood passageway among the plurality of extensions (see Figures 7A, 12A, 12B, 13, and 15A). The hollow tube is sized and shaped so that it is adapted to be and is capable of being implanted in a surface vein and of withstanding the unimpeded intake of fluid for a period of one or more days. Yozu et al disclose the device substantially as claimed. Even though Yozu et al disclose that the device may be used in a number of ways in a patient's body (paragraph [0099]) and, thus, the dimensions (such as length and diameter) of the hollow tube will be selected according to the intended use of the apparatus, Yozu et al are silent on the specifics of the hollow

tube having a length of not more than 10 cm. The instant disclosure describes the parameter of length as being merely preferable, and does not describe it contributing any unexpected results to the tube. As such, the parameter of length is deemed a matter of design choice (lacking in any criticality), well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. It is also well known in the application of medical device that parameters, such as length and diameter, would also be determined by such factors as the patient's size and specific procedure being performed. Applicant should note that in line 28 of page 13 to line 2 of page 14 of Applicant's specification, the length of the hollow tube is disclosed as being less than 10 cm or as being greater than 10 cm (i.e., as calculated when the length of the portion of the hollow tube within the body is added to the length of the portion of the hollow tube that is outside of the body). This disclosure of the length of the hollow tube as being less than or greater than 10 cm is seen as being merely preferable and, therefore, there is a lack in criticality for the parameter of length of the hollow tube.

As to claim 2, the at least one aperture comprises a front inlet at a front end of the hollow tube (123 in Figure 7A). As to claim 3, the at least one aperture comprises one or more side openings in a side of the hollow tube (121, 125 and paragraph [0060]). As to claim 4, the at least one aperture comprises at least one front opening at a front end of the hollow tube and at least one side opening in a side of the hollow tube (121, 123, and 125 in Figure 7A). As to claims 5-10, the movement of at least one of the plurality of extensions of Yozu et al is capable of displacing an impediment in the form

of an aggregate of solid material, a venous valve, or an inflamed body tissue and which is located down flow from the hollow tube or at least partly within the hollow tube. As to claims 11 and 12, the hollow tube of Yozu et al is capable of being implanted in a surface vein for a period of one or more weeks and/or months. As to claims 13-15, 19, and 20, the apparatus includes an activating mechanism which causes at least one of the plurality of extensions to extend from the first position to the second position or to un-extend from the second position to the first position where the activating mechanism is configured for manual activation due to the manual operation of the apparatus and for automatic activation as a result of the delivery of inflation fluid (paragraph [0053]). As to claims 21-24, Yozu et al disclose the claimed structural elements of the device, thus, the device of Yozu et al is capable of being adapted such that delivery of the fluid may be performed before, after, or during the movement of at least one of the plurality of extensions or such that at least some of the movement of at least one of the plurality of extensions takes place irrespective of the delivery of the fluid through the at least one aperture. As to claims 26 and 27, the at least one aperture is covered or arranged to be covered by at least one of the plurality of extensions in the first position (Figures 6, 12B, and 15A). As to claims 32-34, at least one of the plurality of extensions comprises at least one expandable element which expands when filled with expansion fluid, the apparatus includes an activating mechanism with a reservoir (7, 7a) containing expansion fluid which is used to expand the extension. As to claim 39, the plurality of extensions comprises resilient extensions. As to claims 44, 45, and 54, Yozu et al disclose the claimed structural elements of the device, thus, at least one of the plurality

of extensions of Yozu et al is capable of being adapted for an arm vein and for a non-vein vessel. As to claims 46 and 47, the at least two positions are axially displaced and radially displaced. As to claim 51, the hollow tube has a thicker section (11, 111) on the proximal part of the hollow tube that would be located outside of a patient's body and that would prevent entry into the patient's body. As to claim 52, the hollow tube is winged (11, 111). As to claim 53, the hollow tube is a port. As to claim 55, Yozu et al disclose the hollow tube having an outer diameter of 3.6 millimeters (paragraph [0052]). However, as indicated above, the parameter of the diameter of the hollow tube would be deemed a matter of design choice depending on the specific application of the device.

8. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yozu et al in view of Barry (U.S. Patent No. 5,857,998).

Yozu et al disclose the device substantially as claimed. However, Yozu et al are silent on the specifics of the hollow tube or the plurality of extensions comprising a material that is capable of preventing or retarding aggregation of solid from a bodily fluid or clot formation or a body tissue inflammatory response. Barry discloses an apparatus having a hollow tube defining at least one aperture configured for the intake of fluid and located on the hollow tube and at least one extension operative to be at at least two positions with respect to the at least one aperture in the same field of treating the vessel tissues in a patent's body. The apparatus comprises a material that is capable of preventing or retarding aggregation of solid from a bodily fluid or clot formation or body tissue inflammatory response (lines 10-28 of column 8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the

device of Yozu et al with a material to prevent or retard aggregation of solid from a bodily fluid or clot formation or a body tissue inflammatory response as both Yozu et al Barry disclose apparatus for treating body tissues and Barry teaches that it is well known to provide the device with a material such to prevent or retard aggregation of solid from a bodily fluid or clot formation or a body tissue inflammatory response which can lead to complications for the patient undergoing the medical procedure.

9. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yozu et al in view of Zadno-Azizi (U.S. Patent No. 6,958,059).

Yozu et al disclose the device substantially as claimed. However, Yozu et al are silent on the specifics of the device comprising a material that prevents or retards bacteria colonization. Zadno-Azizi discloses an apparatus for treating an impediment which comprises a material which is capable of preventing or retarding bacteria colonization (see line 44 of column 13 to line 6 of column 14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Yozu et al with a material to prevent or retard bacteria colonization as both Yozu et al and Zadno-Azizi disclose apparatus for treating body tissues and Zadno-Azizi teaches that it is well known to provide the apparatus with a material such as an antibiotic to prevent or retard bacteria colonization as bacteria colonization can lead to complications for the patient undergoing the medical procedure.

Allowable Subject Matter

10. Claim 35 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

11. Applicant's arguments with respect to claims 1-15, 19-24, 26-35, 39, 44-47, and 51-55 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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